

<p align="center">DEPARTMENT OF HEALTH AND HUMAN SERVICES</p> <p align="center">PUBLIC HEALTH SERVICE</p> <p align="center">FOOD AND DRUG ADMINISTRATION</p> <p align="center">HOSPITAL REQUEST FOR METHADONE DETOXIFICATION TREATMENT</p>		<p><i>Form Approval: OMB No. 0910-0140</i> <i>Expiration Date: April 30, 2001</i> <i>See Reverse for OMB Statement</i></p>	
		<p align="center">FOR FDA USE ONLY</p>	
		<p>HOSPITAL NUMBER</p>	
		<p>DATE</p>	
<p>NOTE: This form is required by 21 CFR 291.505 pursuant to Sec. 303, Controlled Substances Act (21 USC 823) and Section 4, Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 USC 275(a)). Failure to report can result in a recommendation for the suspension or revocation of the Narcotic Treatment Program registration.</p>			
<p>NAME OF HOSPITAL</p>			
<p>ADDRESS (Include City, State, Zip Code)</p>		<p>TELEPHONE NUMBER (Include Area Code)</p>	
<p>NAME OF PHARMACIST RESPONSIBLE FOR RECEIVING AND SECURING SUPPLIES OF METHADONE</p>			
<p>NUMBER OF BEDS IN HOSPITAL</p>	<p>NUMBER OF BEDS COMMITTED TO METHADONE TREATMENT (May be expressed in parts, such as tenths)</p>	<p>ANTICIPATED NUMBER OF GRAMS OF METHADONE FOR NARCOTIC ADDICT TREATMENT NEEDED ANNUALLY</p>	
<p>Commissioner Food and Drug Administration Division of Scientific Investigations (HFD-342) 5600 Fishers Lane Rockville, Maryland 20857</p> <p>Dear Sir:</p> <p>As hospital administrator, I submit this request for approval to receive supplies of methadone to be used for detoxification treatment in accordance with 21 CFR 291.505 Standards for Drugs Used for Treatment of Narcotic Addicts. I understand that the failure to abide by the requirements described below may result in suspension or revocation of registration to receive shipments of methadone pursuant to the Controlled Substances Act of 1970, as amended by the Narcotic Addict Treatment Act of 1974.</p> <ol style="list-style-type: none"> I. A general description of the hospital including specialized treatment facilities and nature of patient care to be undertaken is attached. II. Methadone or narcotic addict treatment will be administered or dispensed only for detoxification treatment of hospitalized patients. I understand that the approval of this application is not necessary to permit the hospital to maintain or detoxify a person as an adjunct to medical or surgical treatment of conditions other than addiction. III. Accurate records shall be maintained showing dates, quantity, and batch or code marks of the drugs used for inpatient detoxification treatment. The records shall be retained for a period of three years. IV. The Food and Drug Administration, the National Institute on Drug Abuse, and the State authority may inspect supplies of the drug and evaluate compliance with applicable parts of 21 CFR 291.505. The identity of the patient will be kept confidential (<i>except when it is necessary to make follow-up investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records relating to approval of the hospital or any portion thereof</i>). The confidentiality requirements or 42 CFR Part 2 shall be followed. 			
<p>TYPED OR PRINTED NAME OF HOSPITAL ADMINISTRATOR</p>	<p>SIGNATURE OF HOSPITAL ADMINISTRATOR</p>	<p>DATE</p>	

Please send two copies of this form to:

Commissioner
Food and Drug Administration
Division of Scientific Investigations (HFD-342)
5600 Fishers Lane
Rockville, Maryland 20857

and two copies to the appropriate State authority.

Paperwork Reduction Act Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to:

OS Reports Clearance Officer
ASMB/Budget/DIOR (0910-0140)
HHH Building, Room 531H
200 Independence Avenue, SW
Washington, DC 20201

Please **DO NOT RETURN** this form to this address.